# IQ/OQ Protocol
# Installation Qualification/ Operation Qualification

## FreeZone® Triad Stoppering Tray Dryer and Lyophilizer Freeze Dry Systems

*Labconco No: 1059502 Rev. A*
*Available at www.labconco.com*
*or by e-mail in Word 2000 document*

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# Purpose and Scope IQ and OQ

This Qualification Protocol is solely intended to be used with Labconco FreeZone Triad Stoppering Tray Dryers, which are new or relocated. This document is to be used to validate the following models:

**Models:** **FreeZone Triad Stoppering Tray Dryer**

7400030 7400040

This document is written to assist the end-user in validation of predetermined specifications. The protocol begins with planning the site for the piece of equipment and therefore is of value prior to receipt of delivery.

The use of this document does not replace the need for the User's Manuals, (7373300). Information within the User's Manual is required to complete this IQ/OQ Protocol. If the manual has been misplaced, copies can be obtained from the manufacturer or down-loaded from their website, www.labconco.com

# Responsibilities

**End-User** – The ultimate user or otherwise appointed personnel in the lab is responsible to ensure the freeze dryer is installed and operating properly. This document can assist in that validation. This document cannot however anticipate every application or unique situation encountered with the installation and operation. It is therefore essential that users, lab managers and safety officers work together to broaden the scope of this document through careful forethought.

**End-User Employer** – The employer is responsible for supporting the validation through adequate resources and training. The organization shall also ensure the validation process has been fully carried out prior to applying the Triad Stoppering Tray Dryer. Records should be stored in a safe, easily retrievable location. The location of the equipment and required validation should be included in the company's quality system.

**Manufacturer** – Labconco Corporation, certified ISO-9001, is responsible to fully test each Triad Stoppering Tray Dryer prior to shipment. The manufacturer must retain these records. Labconco's staff of Product Service Representatives and Product Specialists can assist with information on the purchase, delivery and installation. Labconco is not responsible for the actual installation or validation processes.

# Performance Qualification

Once the Triad Stoppering Tray Dryer has been checked for proper installation and operation, its performance can be validated. Labconco cannot recommend specific procedures to do this. The performance validation should be designed to meet the specifications and accuracy required of the application.

In general, this requires establishing acceptance criteria, making several runs and testing the results with calibrated equipment and qualified personnel.

# A. Installation Qualification

| Step | Description | Specification or Acceptance Criteria | Result | |
|---|---|---|---|---|
| | | | YES | NO |
| **1** | **Site Planning** | | | |
| 1a | Work surface / stand weight requirements | The Triad Stoppering Tray Dryer weighs 400 pounds. The vacuum pump weighs at least an additional 45 pounds.<br><br>Is the location where the Triad Stoppering Tray Dryer will be located stable and capable of safely supporting the required weight? | Y | N |
| 1b | Space Requirements | Refer to the Appendix in the Triad Stoppering Tray Dryer User's Manual for dimensions of the model you have chosen. Has overhead and working space been provided for the equipment?<br><br>(A minimum of 3-inches is required between the back and sides of a Triad Stoppering Tray Dryer and the wall for proper airflow through the refrigeration system. Additional space is required on the left side if freeze drying will be performed in flasks) | Y | N |
| 1c | Electrical Service | Refer to the User's Manual for electrical requirements. Are services available for the equipment to be connected to an electrical circuit of adequate size and the proper voltage? | Y | N |
| | | All models are shipped with a power cord with NEMA 6-20P plug. Does this match the available receptacle? Is a plug available to match the service outlet at the installation site? | Y<br><br>N/A | N |
| 1d | Optional Features | Serum bottles, ampules, flasks and related accessories are not included with the Triad Stoppering Tray Dryer. Have these been considered / available for this application? | Y | N |

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| | | Is a suitable vacuum pump available or has it been ordered? Refer to the User's Manual<br><br>It must have a displacement of at least 144 liters per minute and be capable of achieving an ultimate vacuum (total pressure) of .002 mBar. The power cord should have a reverse IEC 320 plug to plug into the rear of the Triad | Y | N |
| **2** | **Prior to Operation** | | | |
| 2a | Damage Claims | Have the delivered products been inspected for any signs of damage that may have occurred while in transit? Keep packaging materials until inspection is complete.<br><br>**WARNING: Do not attempt to pull a vacuum on a Triad Stoppering Tray Dryer with any damage to the clear door. Implosion and potential for injury can occur.**<br><br>If damaged, refer to the User's Manual for information on shipping damage claims. | Y | N |
| 2b | Triad Stoppering Tray Dryer Installation | Place the Triad Stoppering Tray Dryer on top of the work surface or stand.<br><br>**Caution: Triad Stoppering Tray Dryers are extremely heavy. Follow safe lifting guidelines.**<br><br>Has the vacuum pump been connected using the rubber hose and clamps provided? | Y | N |
| 2c | Data acquisition using the RS 232 receptacle | Operation of the Triad Stoppering Tray Dryer may be monitored using a computer.<br><br>Interconnect Cable #7537801 with a 25 pin D-sub male serial connector or Cable #7537800 with a 9 pin D-sub male serial connector is available.<br><br>If the Interconnect Cable is required, has it been installed? | Y<br><br>N/A | N |

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| 2d | Electrical Connection | Plug the Tray Dryer into a dedicated electrical outlet. Has the electrical service been verified to be adequate in size, voltage, amperage and frequency? (The ID plate on the rear of the freeze dryer has the electrical requirements.) | Y | N |
| | Electrical Grounding | Has the ground on the electrical service been verified? | Y | N |

# B. Operational Qualification

| Step | Description | Specification or Acceptance Criteria | Result | |
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| | | | YES | NO |
| **1** | **Freeze Dryer** | | | |
| 1a | Start Up | With the:<br>Triad Stoppering Tray Dryer's Power switch ON,<br>Stoppering control in the "raise" position,<br>Vac Release control in the "close" position,<br>Empty serum vials with loose stoppers on the four corners of the shelf,<br>Temperature probe taped to the top-center of the shelf with aluminum tape,<br>Door on the Tray Dryer latched & closed,<br>Vacuum pump plugged into the back of the Triad Stoppering Tray Dryer and its power switch turned on (if so equipped),<br>Room ambient temperature 68°F or cooler,<br>Vacuum set point set at 0.040 mBar,<br>Manual set point system temperature set at -55$^{o}$C,<br><br>With the Triad Stoppering Tray Dryer in the manual mode, press the Run/Stop button and the Vac button.<br>Does the Triad Stoppering Tray Dryer's refrigeration system start?<br><br>Does the vacuum pump start?<br><br>(Allow refrigeration and vacuum pump to continue to operate.)<br><br>Record the time it started. _____ | Y<br><br>Y | N<br><br>N |
| 1b | Cooling of the Shelf and collector | Did the Triad Stoppering Tray Dryer shelf temperature reach -55$^{o}$C, (+/-1 $^{o}$C), within 3 hours of starting? | Y | N |
| | | Did the Triad Stoppering Tray Dryer collector temperature reach -80°C within 1 hours of starting? | Y | N |

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| 1c | Vacuum Leaks | Does the system reach a displayed vacuum level 0.030 to 0.050 mBar in 2 hours? | Y | N |
| 1d | Heating of the Shelves | Raise the set point of the shelves to 50°C and press "Enter" on the Triad Stoppering Tray Dryer.<br><br>Monitor the displayed temperature for the shelves. Does the temperature of the shelves reach 50°C, (+/-1°C) within 1 hour? | Y | N |
| 1e | Automatic Mode | To test the programmability function, set the display to Auto and enter any parameters for a new program, for example:<br>Prefreeze Time 3 hr<br>Segment 1: Ramp 1.5°C/min, Hold -55°C, Time 1.0 hr<br>Segment 2: Ramp 1.5°C/min, Hold 50°C, Time 0.20 hr<br>Segment 3: Ramp 1.5°C/min, Hold 24°C, Time 0.20 hr<br>(Large temperature swings and long hold times will prolong the test.)<br><br>Run the new program. Does the vacuum pump turn ON when Prefreeze is completed?<br><br>Continue with the program. | Y<br><br>N/A | N |
| 1f | Automatic Mode | Does the system's temperature rise and fall as programmed? | Y<br><br>N/A | N |

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| 1g | Verify Displayed Temperature | The shelf temperature indicated on the LCD display during Manual and Auto Segments 1 thru 5 is measured where the heat transfer fluid enters the shelves. The collector temperature is measured where the refrigerant leaves the collector. The values were calibrated at the factory by correlating readings with that of a reference gauge attached to thermocouples inside the rear of the machine. The T-type (red/blue) thermocouples can be accessed only by removal of the back cover of the Triad Stoppering Tray Dryer.<br><br>**CAUTION: Electrical Shock Hazard – Disconnect power to the unit prior to removal of any covers.**<br><br>Does the collector display correlate to the reference gauge/meter +/- 2°C?<br><br>Does the Shelf display correlate to the reference gauge/ meter +/- 2°C<br><br>Ref. Instrument? _____<br><br>If the temperature does not correlate, contact Labconco Product Service for calibration procedure. | Y<br>N/A<br><br>Y<br>N/A | N<br><br>N |
| 1h | Stoppering Operation | Rotate the Stoppering knob to the “lower” position.<br><br>Did the top platen slowly lower from the top and did each serum vial seal with the stoppers? | Y<br><br>N/A | N |
| | | Rotate the Stoppering knob to the “raise” position.<br><br>Did the platen return to its highest position? | Y<br><br>N/A | N |

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| 1i | Temperature Probes | The shelf temperature probe can be verified by placing it into an ice bath. Agitate a crushed ice and water bath and place the temperature probes into it.<br><br>Does the displayed temperature read between $1^{o}C$ and $-1^{o}C$?<br><br>If the temperature does not correlate, contact Labconco Product Service for calibration procedure. | Y<br><br>N/A | N |

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| 1j | Verify Displayed Vacuum | The vacuum level indicated on the LCD display is measured at the rear of the chamber. The value was calibrated at the factory by correlating its reading with that of a reference gauge. The calibration was performed at a very low level, approximately 0.010 mBar.<br><br>NOTICE: Factory calibration was performed using a precision Active Piranni Gauge calibrated to a Capacitance Manometer standard. Despite the system's calibration and repeatability, the readings taken at such a low level of vacuum should only be considered as a verification of a leak-free system. Vacuum swings can be attributed to contamination of surfaces, which could take days to outgas. Adjustments are discouraged.<br><br>Before any adjustments are made to the factory calibration of the vacuum measurement, answer positively to each of these questions:<br><br>1) Is the vacuum standard being used to verify the freeze dryer accepted by the organization to be precise and has it been calibrated recently?<br>2) Is the level of accuracy we are attempting to reach pertinent to the freeze drying applications?<br><br>Does the vacuum display correlate to the reference gauge?<br><br>Ref. Instrument? _____<br><br>If vacuum is to be calibrated, contact Labconco Product Service for calibration procedure. | Y<br><br>N/A | N |

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| **2** | **Routine Maintenance** | Below are helpful hints to be included in the organization's preventive maintenance plan. | | |
| 2a | Vacuum Grease | Vacuum grease should be applied to rubber components as required. In general, vacuum grease should be the first step in troubleshooting vacuum leaks. Thin layers of grease are adequate for all seals. Only use grease specially formulated for low vacuum service. Grease is not required on the door gasket. Use grease only on the inner and outer sealing surfaces of the rubber manifold valve body.<br>Is vacuum grease readily available and documented?<br>Type of grease used? _____ | Y | N |
| 2b | Inspect for Wear & Damage | Has there been a procedure to periodically inspect the interior metal surfaces for corrosion due to acids? | Y | N |
| | | Are there awareness and a maintenance procedures to check the clear acrylic door for chips, cracks, deep scratches or chemical attack?<br><br>WARNING: This is a safety issue. Implosion can occur with damaged or corroded components! | Y | N |
| | | Will all the rubber components be periodically inspected so that they are free from drying, cracks or deterioration? | Y | N |
| 2c | Refrigeration System Cleaning | At least annually, will the refrigeration condenser be cleaned of dust that would restrict free airflow? (Include in the preventive maintenance schedule) | Y | N |
| 2d | Heat Transfer Fluid | Annually check the fluid level of the Lexsol$_{TM}$ heat transfer fluid with the label applied to the side of the reservoir.<br><br>Has this been included in the preventive maintenance plan? | Y<br><br>N/A | N |

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| **3** | **Personnel Training** | | | |
| 3a | User Training Related to Equipment | Have personnel that will use the Triad Stoppering Tray Dryers been adequately trained?<br><br>Are personnel familiar with:<br>All the buttons, knobs and displays on the control panel;<br>The use of vacuum grease;<br>Opening, closing and venting samples;<br>Cleaning of the freeze dryer and neutralization of acids? | Y | N |
| 3b | User's Manual | Are the personnel who are to use or maintain the Triad Stoppering Tray Dryers able to locate the User's Manual for the machine? | Y | N |

# C. Summary

**Labconco FreeZone Triad Stoppering Tray Dryers IQ/OQ Document 1059502 Rev -**

**Equipment Location _____**

**FreeZone Ser. No. _____ Model No._____**

**User Protocol _____ Revision (or Date published) _____**

**Contact (print name):_____**
**Title: _____**

**Review the "Response" columns for answers of "NO." Use the area below to describe the deficiency or unacceptable results. Those deficiencies are to be followed with an instruction for "Corrective Actions." Once acceptable results are obtained, the deficiency is "accepted" by initialing the Corrective Action.**

| Step | Deficiency followed by Corrective Action | Initial |
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